REMARKS

Claims 2-3, 5-6, 8, and 11-24 are pending in the present application. Claim 2 has been amended to correct a typographical error.

Summary of Examiner Interview

Applicants thanks Examiners' Arnold and Richter for the courtesies extended during the in-person interview of January 29, 2008 where the present claims were discussed. Applicants discussed how not all fetal or neonatal patients that experience pain are in need of analgesia. Applicants indicated that they would present evidence to support this position. Applicants are doing so by the attached declaration (Exhibit A) and article (Exhibit B).

Rejection of Claims Under 35 U.S.C. 112

Claim 2 stands rejected for allegedly lacking antecedent basis for the term "fetal subject." This claim has been amended and Applicants request withdrawal of this rejection.

Rejection of Claims Under 35 U.S.C. 102 by Fukara

Claims 2, 11-13 and 17 stand rejected as being allegedly anticipated by Fukara et al. (Prog. Neuro-Psychopharmacol. & Biol Psychiat., 2004, 24, 1357-1368) ("Fukara"). Applicants traverse this rejection.

According to the Examiner, Fukara discloses treating pregnant rats and neonatal rats with an anesthetic xenon gas mixture. Further, according to the Examiner, "xenon acts as both an anesthetic and analgesic because it is an inherent property of xenon." Whether xenon inherently acts as an analgesic is simply not a germane inquiry with respect to this 102 rejection as both claims 11 and 12 are directed to methods of providing analgesia by administering xenon to a fetal or newborn subject in need thereof. Unless, Fukara describes administering xenon to this specific patient population to provide analgesia, the point that xenon inherently acts as both an analgesic and an anesthetic is not relevant because the present claims are directed to a method of treating a specific patient population. This specific patient population is simply not disclosed in Fukara.

Rejection of Claims Under 35 U.S.C. 102 by Lane

Claims 12, 17 and 21 stand rejected as being allegedly anticipated by Lane et al. (Science 190, 210(4472), 899-901) ("Lane"). Applicants traverse this rejection.

As Applicants stated before, there is absolutely no mention of administering xenon to a mother of a fetal subject where the fetal subject is in need of analgesia, as recited by claim 12. In response to this position, the Examiner stated that "the human fetus and newborn are known to experience pain" and that "during birthing, the fetus is subjected to mechanical stress which results in the activation of pain pathways." The Examiner therefore concludes that every fetus about to be born and newborn is in need of analgesia for the alleviation of the pain associated with childbirth. Applicants take issue with this position. While it is true that fetuses may experience pain during childbirth, not every fetus or newborn experiences sufficiently severe pain or stress to warrant administration of an analgesic agent. As with all pharmaceutical compositions, xenon would only be administered to those patients in need and not all fetuses and newborns who experience pain (because of the mechanical stresses during childbirth) are necessarily in need of analgesia.

This position is further supported by the declaration of Dr. Aubrey Maze, a pediatric anesthesiologist, which is provided in Exhibit A. This declaration provides an outline of exemplary conditions and procedures that would necessitate delivery of an analgesic to newborns or fetuses. As is apparent from this declaration, only a sub-population of fetuses and newborns would receive an analgesic agent before, during or after childbirth. Applicants also submit as Exhibit B an article that describes how newborns delivered via instrumentation, such as forceps, experience more stress than those delivered without instrumentation. This is another example of a sub-population of newborns that are in need of analgesia.

Therefore, while newborns may experience pain during delivery, this is not enough to warrant administration of an analgesic agent to these newborns. Accordingly, Applicants submit that Lane does not describe administering xenon to newborns or fetal subjects (via their mothers) in need of analgesia.

Rejection of Claims Under 35 U.S.C. 103 by Fukara in view of Georgieff and Fishman

Claims 2, 3, 5, 6, 8 and 11-24 stand rejected as being allegedly rendered obvious by Fukara in view of U.S. Patent No. 6,197,323 to Georgieff ("Georgieff") and U.S. Patent No. 5,099,834 to Fishman ("Fishman") and further in view of Ohashi. Applicants traverse this rejection.

As Applicants stated in their previous response, Fukara does not describe administering xenon to a newborn or fetal subject in need of analgesia. Further, neither Georgieff nor Fishman describe this subject matter. Georgieff is directed to a liquid xenon emulsion that can be used as an anesthetic (See Abstract). Although Georgieff mentions that xenon has an analgesic action, there is no indication of using xenon as an analgesic in a fetal or newborn subject in need of analgesia. With respect to Fishman, this reference does not cure the deficiencies of Georgieff as this reference does not describe using xenon to provide analgesia to a newborn or fetal subject in need thereof. Rather, Fishman mentions using xenon as an anesthetic throughout (See e.g., Abstract; col. 2, lines 54-55; col. 4, lines 28-30; and col. 5, lines 37-43).

As with the rejection based on Fukara (discussed above), the Examiner asserts that "administering xenon to pregnant, fetal and newborn subjects would all benefit from the intrinsic [analgesic] properties of xenon." Again, Applicants are claiming a method of providing analgesia to neonatal and fetal subjects in need thereof. Just because xenon inherently has analgesic properties does not mean there is any teaching or suggestion that xenon should be administered to a certain sub-population of neonatal and fetal subjects . There needs to be some reason in the art for providing xenon to these particular patients in order to justify this obviousness rejection. Further, just because xenon may be used as an analgesic in an adult patient does not mean that it can or should be used as an analgesic in a fetal or newborn subject in need of analgesia.

For instance, as described in the present specification:

> the expectation that efficacious analgesic drugs in adults will exert the same beneficial effects in neonates has been challenged by our recent report that nitrous oxide (N_2O) is ineffective in neonatal rats because the immature pain pathways cannot activate the descending inhibitory pathway in response to nociceptive stimuli. . . Experiments have shown that N_2O lacks antinociceptive effects against thermal.. . and inflammatory. . . stimulation in rats under 3 weeks of age. If extrapolatable to humans, this would mean

that N_2O is ineffective as an analgesic agent in subjects up to and including the toddler stage. A similar rationale was thought to apply to the use of xenon as an analgesic agent.

Therefore, not only is there reason to doubt whether xenon would be efficacious as an analgesic agent in fetal and neonatal subjects, but there is also no suggestion of using xenon in such patients who are in need of analgesia.

CONCLUSION

It is respectfully submitted that the present application is now in condition for allowance, which action is respectfully requested. The Examiner is invited to contact Applicants' representative to discuss any issue that would expedite allowance of the subject application.

Any fees for extension(s) of time or additional fees required in connection with the filing of this response, are hereby petitioned under 37 C.F.R. § 1.136(a), and the Commissioner is authorized to charge any such required fees or to credit any overpayment to Kenyon & Kenyon's Deposit Account No. 11-0600.

Respectfully submitted,
KENYON & KENYON LLP

Dated: July 14, 2008 By: /Zeba Ali/
Zeba Ali
(Reg. No. 51,392)

1500 K Street, N.W.
Suite 700
Washington, D.C. 20005
Tel: (202) 220-4200
Fax: (202) 220-4201

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